IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

TIMOTHY SMITH, ROHIT FEDANE, and MISTY JOHNSON, individually and on behalf of all others similarly situated, Plaintiffs, v. CABOT CREAMERY COOPERATIVE, INC. and AGRI-MARK, INC., Defendants.	Case No. 12-4591 SC ORDER GRANTING MOTION TO DISMISS

I. INTRODUCTION

Plaintiffs Timothy Smith, Rohit Fedane, and Misty Johnson ("Plaintiffs") filed a putative class action lawsuit against Defendants Cabot Creamery Cooperative, Inc. ("Cabot") and its parent Agri-Mark, Inc. ("Defendants"), asserting a variety of statutory and common law claims. ECF No. 16 ("FAC"). Plaintiffs' claims are all based on the core allegation that Defendants' yogurt product, which Plaintiffs purchased, was misbranded under federal food regulations. See id. ¶¶ 1-6. Now before the Court is Defendants' motion to dismiss Plaintiffs' FAC. ECF No. 22 ("MTD").

The motion is fully briefed, ECF Nos. 27 ("Opp'n"), 32 ("Reply"), and suitable for decision without oral argument, Civ. L.R. 7-1(b). For the reasons discussed below, Defendants' motion is GRANTED, and Plaintiffs' claims are DISMISSED WITH PREJUDICE.

II. BACKGROUND

Yogurt is a dairy product made by combining milk with certain food-grade bacteria. FAC ¶¶ 16-18. The bacteria ferment the milk's lactose to produce lactic acid. Id. This fermentation process causes the milk to coagulate and thicken into a liquid-solid mixture. Id. "Regular" yogurt maintains both the liquid and solid portions of the yogurt manufacturing process, while Greek yogurt keeps only the solid. Id. ¶¶ 19-20. As a result it is thicker, higher in protein, and lower in sugar than regular yogurt. Id. ¶ 20. It also tends to be more expensive than regular yogurt. Id. ¶ 5.

Cabot markets "Cabot Greek," the product at issue in the instant matter, as "Greek-Style YOGURT." Id. ¶ 22. Cabot Greek contains whey protein concentrate ("WPC") and milk protein concentrate ("MPC"). Id. ¶ 26. WPC and MPC are concentrated protein powders that are essentially byproducts of cheese manufacturing. Id. ¶ 28. If the protein powder contains mostly whey protein, it is WPC. Id. ¶ 29. If it contains whey and casein proteins in the same proportion as they appear in cow's milk, it is MPC. Id. Plaintiffs allege that Cabot uses WPC and MPC as "filler material" to thicken Cabot Greek and increase its protein content, instead of making Greek yogurt the "authentic" way, which involves filtering the liquid whey byproduct during the manufacturing

process and keeping only the protein-rich solid portion. Id. ¶¶ 1-2, 20-21, 27-29, 32.

Plaintiffs are all consumers who purchased Cabot Greek believing it to be yogurt. FAC ¶ 6. According to Plaintiffs, the problem with Cabot Greek's manufacturing process arises from the Food and Drug Administration's ("FDA") strict guidelines, called Standards of Identity ("SOI(s)"), which define what may legally be called "yogurt." Id. ¶¶ 37-40. Plaintiffs allege that Cabot Greek is not "yogurt" under FDA regulations and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 341, because it contains MPC and WPC, which Plaintiffs claims the FDA forbids as ingredients in yogurt. Id. ¶¶ 35-36, 43-44. Plaintiffs allege that Cabot's branding misled them into believing that they were purchasing genuine Greek yogurt and thereby paying a premium for it, which they would not have done if it were not so branded. See id. ¶¶ 5-6, 36.

Per these allegations, Plaintiffs bring the following causes of action against Cabot: (1) breach of express warranty; (2) breach of the implied warranty of merchantability; (3) breach of the implied warranty of fitness for a particular purpose; (4) unjust enrichment; (5) violation of California's Consumer Legal Remedies Act ("CLRA"), Cal. Civ. Code sections 1751 et seq.; (6) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code sections 17200 et seq.; (7) violation of California's False Advertising Law ("FAL"), Cal. Bus. & Prof. Code sections 17500 et seq.; (8) negligent misrepresentation; and (9) fraud.

Defendants now move to dismiss Plaintiffs' FAC, arguing primarily that the FDA permits the addition of MPC and WPC to

yogurt, thereby rendering all of Plaintiffs' claims baseless because they are predicated on the FDA's purported prohibition of those ingredients. MTD at 6-15.[1]

III. LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) "tests the legal sufficiency of a claim." Navarro v. Block, 250 F.3d 729, 732 (9th Cir. 2001). "Dismissal can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory." Balistreri v. Pacifica Police Dep't, 901 F.2d 696, 699 (9th Cir. 1988). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). A court's review is generally "limited to the complaint, materials incorporated into the complaint by reference, and matters of which the court may take judicial notice." See Kourtis v. Cameron, 419 F.3d 989, 994 n.2 (9th Cir. 2005).

///

[1] Defendants assert a variety of other grounds for the FAC's dismissal, MTD at 15-18, but since the Court resolves the instant matter on Defendants' main argument, the Court need not and does not address Defendants' remaining arguments.

IV. DISCUSSION

The parties' dispute is ultimately based on one predicate issue: whether FDA regulations forbid cultured dairy products containing WPC and MPC from being called "yogurt." Plaintiffs say they do. Defendants say they do not. Defendants are right. Since all of Plaintiffs' claims are premised on the FDA forbidding the addition of WPC and MPC to yogurt, all of Plaintiffs' claims fail.

A. The Relevant FDA Regulations

The FDA promulgated its first SOIs for yogurt in 1981. 21 C.F.R. §§ 131.200 (yogurt), 131.203 (lowfat yogurt), 131.206 (nonfat yogurt). These SOIs became effective July 1, 1983. 46 Fed. Reg. 9924; 47 Fed. Reg. 41519. The yogurt SOI specifies:

> Yogurt is the food produced by culturing one or more of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, Lactobacillus bulgaricus and Streptococcus thermophilus. One or more of the other optional ingredients specified in paragraphs (b) and (d) of this section may also be added. When one or more of the ingredients specified in paragraph (d)(1) of this section are used, they shall be included in the culturing process. All ingredients used are safe and suitable.

21 C.F.R. § 131.200(a).

The "optional dairy ingredients" that may be cultured per paragraph (c) of the yogurt SOI are "cream, milk, partially skimmed milk, or skim milk, used alone or in combination." Id. § 131.200(c). Paragraph (b) permits the addition of Vitamins A and D. Id. § 131.200(b). Paragraph (d) permits the addition of "other optional ingredients," including (1) "[c]oncentrated skim milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins,

lactoglobulins, or whey modified by partial or complete removal of lactose and/or minerals . . . ," as well as (2) nutritive carbohydrate sweeteners, (3) flavoring ingredients, (4) color additives, and (5) stabilizers. Id. § 131.200(d)(1)-(5). Notably, this list of other ingredients does not include MPC or WPC. See id. § 131.200(d)(1)-5). However, in 1982, the FDA stayed paragraph (d)(1) of the SOI, and so despite being published that portion is not in effect. Stay of Effective Date of Certain Provisions, 47 Fed. Reg. 41519-01 (Sept. 21, 1982) ("1982 Stay").

Plaintiffs allege that the SOI for yogurt, absent the stayed provision, "is an exclusive list of ingredients that may be added to yogurt," and that "if 'yogurt' contains any ingredient not on that list, as a matter of federal law it is not yogurt . . . ." FAC ¶ 43. Plaintiffs further claim that since the yogurt SOI does not include WPC or MPC, those ingredients are prohibited. Id. ¶ 44. Therefore, Plaintiffs aver, Cabot Greek is not yogurt at all and is misbranded per FDA regulations and the FDCA. See id. ¶¶ 35-36, 43-44. This allegation is the basis for all of Plaintiffs' claims. See id. ¶¶ 68-70, 76-83, 86-89, 92-94, 97-102, 109-113, 116-120, 123-28, 131-33.

Defendants' primary argument in moving to dismiss the FAC is that Plaintiffs' claims all fail because the FDA actually permits WPC and MPC as optional ingredients in yogurt. In support of this argument, Defendants point to several FDA statements, made consistently over the last thirty years, in which the agency has interpreted the effect of the stay and the remaining parts of the yogurt SOI. MTD at 6-11.

In 1982, the FDA stated, "[The FDA] is staying the effective

date of the provision[] of [§ 131.200(d)(1)] that restricts the kinds of safe and suitable milk-derived ingredients that may be used as optional ingredients to increase the nonfat solid contents of [yogurts] . . . ." 1982 Stay at 41519. Defendants note that this was the earliest date on which the FDA explained the effect of the 1982 Stay, which was not -- as Plaintiffs allege -- to render the remaining provisions of the yogurt SOI exclusive lists of ingredients, but rather to remove a restriction on what could be added to yogurt. Id.; see Reply at 2-3.

In 2004, the FDA published a Memorandum of Information on its website, which included the following question and answer:

> Q: May whey protein concentrate (WPC) and/or milk protein concentrate (MPC) be used as ingredients in yogurt to increase the nonfat solids content?
>
> A: Yes. 21 C.F.R. 131.200(d), which would have precluded WPC or MPC use, was one of several provisions of the standard of identity for yogurt that were stayed in 1982, 47 F.R. 41519, September 21, 1982.
>
> NOTE: If WPC and MPC are used in Grade "A" yogurt product, they must be Grade "A" and come from an IMS Listed Source.

ECF No. 33, ("RJN") Ex. A ("2004 Interpretation").[2]

In 2009, the FDA proposed amendments to the yogurt SOI. Proposal to Revoke the Standards for Lowfat and Nonfat Yogurt and to Amend the Standard for Yogurt, 74 Fed. Reg. 2443-02 (Jan. 15, 2009) ("2009 Proposal"). In the 2009 Proposal, the FDA noted that it had stayed parts of the yogurt SOI that "restricted the type of

[2] Defendants submitted a Request for Judicial Notice ("RJN"), ECF No. 33, in support of their motion to dismiss. Plaintiffs do not oppose the request and the documents contained in the RJN are public records. The Court GRANTS Defendants' request and takes judicial notice of the documents.

milk-derived ingredients that may be used to increase the nonfat solids content of cultured milk and yogurts." Id. at 2444 (citing 1982 Stay at 41523). As Defendants note, this was the same construction -- removal of a restriction rather than the narrowing of an exclusive list -- that the FDA offered in 1982. Compare id. with 1982 Stay at 41519. The FDA elaborated, "To date, due to competing priorities and limited resources, FDA has not held a public hearing to resolve these issues and the effective date for these provisions remains stayed. Therefore, these provisions were never in effect." Id. Thus, the FDA concluded:

> [C]ultured milk and yogurts may deviate from the relevant standards in the previously mentioned respects. For example, although the current standards do not permit the use of certain ingredients such as preservatives or a reconstituted dairy ingredient as a basic ingredient, because of the stayed provisions, FDA has not taken enforcement action against the use of these ingredients in yogurt, lowfat yogurt, or nonfat yogurt.

Id.

Defendants claim that these express statements are controlling interpretations of the FDA's own regulations, thereby clarifying that WPC and MPC may lawfully be used as optional ingredients to increase the nonfat solid content of yogurt, as Cabot did. See MTD at 7-8, 10. To support this point, Defendants rely mainly on two cases: PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575, reh'g denied, 132 S. Ct. 55 (2011), and Bassiri v. Xerox Corp., 463 F.3d 927, 930 (9th Cir. 2006).

In PLIVA, the parties disputed whether and to what extent generic drug manufacturers could change their drugs' labels after FDA approval. 131 S. Ct. at 2575. The defendants argued that FDA

regulations allowed them to change their drugs' labels without waiting for preapproval, which is ordinarily necessary when a drug company changes a label, but the FDA interpreted its regulations to bar changes without preapproval. Id. The Supreme Court held on this issue that "[t]he FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s] or there is any other reason to doubt that they reflect the FDA's fair and considered judgment.'" Id. (quoting Auer v. Robbins, 519 U.S. 452, 461, 462, (1997)).

In Bassiri, the Ninth Circuit reviewed a district court's decision to give deference to several Department of Labor letters defining the term "normal compensation." 463 F.3d at 930. The district court had given those letters deference under Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944), which sets the standard for courts' deference to agency interpretations of statutes. Bassiri, 463 F.3d at 930. The Ninth Circuit held that because the Department of Labor was interpreting regulations, not statutes, the district court should have applied the Supreme Court's rule from Auer (the same rule the Supreme Court applied in PLIVA, 132 S. Ct. at 2575), which is that "where an agency interprets its own regulation, even if through an informal process, its interpretation of an ambiguous regulation is controlling under Auer unless 'plainly erroneous or inconsistent with the regulation.'" Id. (quoting Auer, 519 U.S. at 461).

Plaintiffs do not grapple with these cases, but they attempt to dull the effect of the FDA's 2004 Interpretation by arguing that the source of the 2004 Interpretation -- a Q&A session at the 2004 Regional Milk Seminar -- renders the 2004 Interpretation merely

informal and, under Supreme Court precedent, "at most, informal statements of policy," which Plaintiffs claim would not be binding in the way a formal regulation would be. Opp'n at 12-13 (citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)). This distinction is not relevant. Chevron does not bar the Court from giving the FDA's clarifications deference, and agencies are not bound to limit their pronouncements to formal rulemaking, as the Supreme Court has made clear: "[B]ecause agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretative statements, and responses to comments, we can expect that they will make their intentions clear if they intend for their regulations to be exclusive." Hillsborough County v. Automated Med. Labs., 471 U.S. 707, 718 (1984). PLIVA provides further guidance: "Where an agency interprets its own regulation, even if through an informal process, its interpretation of an ambiguous regulation is controlling under Auer unless 'plainly erroneous or inconsistent with the regulation.'" 132 S. Ct. at 2575 (quoting Auer, 519 U.S. at 461).

Defendants correctly note that the "informal comments" from the meeting Plaintiffs mention were indeed formalized into a Memorandum of Information from the FDA, directed to "All Regional Food and Drug Directors." 2004 Interpretation. This renders those comments far more compelling than Plaintiffs would suggest. In any event, the FDA is permitted to clarify its regulations as it did in the 2004 Interpretation, and those clarifications are entitled to deference. See Hillsborough, 471 U.S. at 718. Further, the FDA's guidance from the 2004 Interpretation indicates that the FDA

understands its own guidelines to allow WPC and MPC as optional ingredients in yogurt.

Further, per Auer, the FDA's statements in 2004 and 2009 show that it was interpreting its own ambiguous regulation regarding the yogurt SOI. Plaintiffs' contention that "the regulations are completely unambiguous," Opp'n at 12, is plainly false given the posture of this case. The parties would likely not be engaged in such heated argument over the effects of the yogurt SOIs and the FDA's interpretation of them if the yogurt SOIs on their own were as easy to interpret as Plaintiffs claim. Moreover, the regulation is ambiguous by definition because the FDA's stay of the "optional ingredients" provision could suggest either that "optional ingredients" are excluded entirely from the yogurt SOI, or potentially included by virtue of the stay.

The FDA clarified in the 2004 Interpretation and the 2009 Proposal that though it has not made a definitive ruling on the subject, it considers WPC and MPC acceptable optional ingredients in yogurt. These interpretations are entitled to deference, being statements from the FDA about its own regulations. The Court therefore finds that MPC and WPC are permissible optional ingredients in yogurt under FDA regulations. Plaintiffs' claims all fail because they are premised on the argument that those ingredients are impermissible. Defendants' motion to dismiss is GRANTED for these reasons.

B. Plaintiffs' Other Arguments

Plaintiffs provide four additional arguments for why the FDA regulations do not actually allow WPC or MPC in yogurt. These arguments are all unconvincing on their own.

First, Plaintiffs argue that the FDA has unambiguously stated that WPC and MPC are forbidden in yogurt. Opp'n at 10-13. The statements to which Plaintiffs refer actually concern the FDA's clarification that WPC and MPC are not allowed as basic ingredients in yogurt. See 2009 Proposal at 2452-53. This is irrelevant. Defendants' argument is that the FDA permits WPC and MPC as optional ingredients, which is how they are used in Cabot Greek. The two categories of ingredients, basic and optional, are factually and legally different and should not be conflated.[3]

Second, Plaintiffs' argument that the 1982 Stay renders the yogurt SOI an "exclusive list" of acceptable ingredients fails because the FDA, as discussed in Section IV.A supra, has stated otherwise, and its interpretation of its regulation is binding. Further, Plaintiffs' authority here is inapposite. Plaintiffs rely on the following language from the Supreme Court's decision in Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218, 232 (1943): "The announcements promulgating [the SOIs in question] stated that they were so framed as to exclude substances not mentioned in the definition." Opp'n at 6. But this language actually undermines Plaintiffs' position. The FDA never stated that substances not mentioned in the yogurt SOIs were excluded from

[3] In support of their argument on this point, Plaintiffs also cite FDA statements regarding "cheese food" products, in which the FDA stated clearly that MPC cannot be added to "cheese foods" as an optional ingredient. FAC ¶ 45. These statements are irrelevant to the instant matter. Cheese foods and yogurt have different SOIs, and the FDA's statements on one should not be taken to apply to the other. Plaintiffs disagree, claiming that the FDA explained that its findings on WPC and yogurt were "consistent with the agency's recent tentative decision not to permit [MPC] as a basic ingredient in standardized cheese," but that quotation concerned basic ingredients, not optional ingredients, and as the Court has noted, the two categories are not to be conflated. See Opp'n at 12 (citing 2009 Proposal at 2452-53).

yogurt. As discussed in Section IV.A supra, it did the opposite. Further, the SOIs in question in Quaker Oats specifically forbade the food producer in that case from using the certain ingredients in the product it produced. See Quaker Oats, 318 U.S. at 220-23. That is not the issue here.

Third, Plaintiffs argue that the FDA's failure to enact any rules explicitly permitting WPC and MPC in yogurt from the 2009 Proposal means that the FDA meant to indicate that WPC and MPC had always been prohibited in yogurt. See Opp'n at 11. This is unconvincing. The FDA had interpreted its regulations to permit WPC and MPC in yogurt in 1982 and 2004, and even in the 2009 Proposal itself. See 2009 Proposal at 2444; see also Section IV.A, supra (discussing the 2009 Proposal). Plaintiffs misleadingly cite a section of the 2009 Proposal in which the FDA clarifies that WPC and MPC are forbidden as basic ingredients, an argument the Court rejected above. See Opp'n at 11 ("[The National Yogurt Association] requested that FDA revise the yogurt standards to allow the use of [WPC] as a basic ingredient . . . ."") (citing 2009 Proposal at 2452-53) (emphasis added). But this section says nothing at all about optional ingredients.

Finally, Plaintiffs allege that WPC and MPC render Cabot Greek "adulterated" because they are food additives, and moreover, are not Generally Recognized as Safe ("GRAS"), thereby violating the FDCA. FAC ¶¶ 46-51. This argument is also unavailing. The FDA has stated specifically that MPC and WPC are permissible optional ingredients in yogurt. It would not have made this statement so clearly if that same permissible addition would render the yogurt illegally adulterated.

V. CONCLUSION

For the reasons discussed above, the Court GRANTS Defendants Cabot Creamery Cooperative, Inc. and Agri-Mark, Inc.'s motion to dismiss Plaintiffs Timothy Smith, Rohit Fedane, and Misty Johnson's first amended complaint. Plaintiffs' complaint is DISMISSED WITH PREJUDICE.

IT IS SO ORDERED.

Dated: February 25, 2013

UNITED STATES DISTRICT JUDGE